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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,221	11/06/2001	Tomohiro Tsuji	3029-75	7242

7590

05/29/2003

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EXAMINER

WEBER, JON P

ART UNIT

PAPER NUMBER

1651

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DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/992,221

Applicant(s)

TSUJI ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

The response with amendments filed 04 March 2003 has been received and entered.
Claims 1-10 have been presented for examination.

Claim Rejections - 35 USC § 103

Claims 1-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Inami et al. (US 5,298,426) in view of Kim et al. (US 5,559,037), Hansen et al. (US 4,284,412), Hoffman et al. (US 4,492,752) and newly added Bentley (1995) and further in view of Kim et al. (US 5,516,695).

The teachings of Inami et al. (US 5,298,426), Kim et al. (US 5,559,037), Hansen et al. (US 4,284,412), Hoffman et al. (US 4,492,752) and Kim et al. (US 5,516,695) have been discussed in the Office action of 27 November 2002.

It is argued that none of Inami et al. (US 5,298,426), Kim et al. (US 5,559,037), Hansen et al. (US 4,284,412), Hoffman et al. (US 4,492,752) or Kim et al. (US 5,516,695) teaches classifying the fat particles in the process of making TNC count.

Bentley (1995) teach the importance of classifying fat particles in a flow cytometry method of counting total nucleated cells (TNC) in aspirated bone marrow so as to eliminate the fat particles from the TNC count. As can be seen in Figures 1 and 2, the fat particles are clearly delineated from the cells. Figure 2 shows how by rearranging the threshold lines, the fat particles can be assigned to boxes that are easily subtracted from the TNC. With the existing equipment, a Cobas-Helios device, the threshold lines had to be modified manually, which was less than satisfactory. However, at page 64, first full paragraph it is suggested that automated software

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could be developed to perform this task more consistently. In the conclusion it was suggested that manufacturers update their software to fully automate the TNC counts.

In the method of Bentley et al., the continuous flow sample is mixed with a proprietary reagent that lyses the RBCs, fixes the white cells with minimal distortion and stains the intracellular granules. The Cobas-Helios device then measures two parameters, absorbance and cell size, simultaneously to obtain the scattergram. The absorbance was based on stained cells (comparable to instantly used fluorescence, but a different dye). The cell size was based on aperture impedance (comparable to light scattering).

Newly cited Bentley et al. (1995) establishes the importance of classifying the fat particles in a bone marrow sample so that an accurate TNC count can be obtained. A method for practicing the classification and TNC count is disclosed in Bentley et al. (1995). Although Bentley et al. use different observables in the determination of the TNC count than instantly, these are recognized in the art to be functional equivalents to those instantly used. A similar scattergram is obtained because the same underlying parameters are being measured, cell type specific staining and cell size. It is proper to combine Inami et al. (US 5,298,426) with Bentley et al. because they are both directed to solving the same problem, obtaining accurate TNC counts from aspirated bone marrow.

Applicant's arguments filed 04 March 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103(a) is adhered to for the reasons of record and the additional reasons above.

The prior art made of record in the IDS of 04 March 2003 and not relied upon is considered pertinent to applicant's disclosure.

Tsuji et al. (EP 1,004,880) practices the similar steps as instantly claimed of lysing, differential fluorescent staining of cells, and scattergrams obtained from fluorescence and low angle forward scattering, except with peripheral blood and circulatory system samples instead of bone marrow samples. Fat particles are not seen or classified.

D'Onofrio et al. (1998) and Fan et al. (1999) both use an algorithm describe elsewhere (D'Onofrio et al., 1997, Lab Hematol., 3:138) to account for fat particles during bone marrow TNC counts. The details are not provided in these articles. Both these references establish the tight correlation between results with bone marrow and peripheral blood TNC counts.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

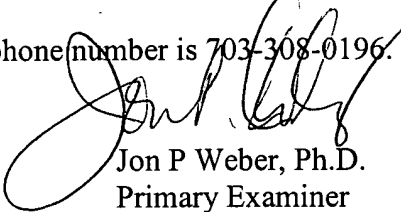
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
May 22, 2003